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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/852,495	05/07/97	RUDDY D	17957-000110

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EXAMINER	
VANDER VEGT, F	
ART UNIT	**PAPER NUMBER**
1644	27

DATE MAILED: 04/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/852,495	Ruddy et al
Examiner	**Art Unit**
F. Pierre VanderVegt	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 1, 2001*

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *29-79* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *29-79* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

This application is a continuation-in-part of application S.N. 08/724,394, which is a continuation-in-part of application S.N. 08/630,912, which is a continuation-in-part of application S.N. 08/652,265.

New claims 49-79 have been added.

Claims 29-79 are currently pending in this application.

Double Patenting

1. In view of the terminal disclaimer filed February 1, 2001 over the signature of Applicant's representative Gary S. Williams the non-statutory obviousness-type double patenting rejection is hereby withdrawn.

2. In view of the amendment filed February 1, 2001, only the following rejections are maintained.

Claim Rejections - 35 USC § 112

3. Claims 29-48 and 69-79 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It was stated previously: "Summarizing the ranges claimed in base claims 29, 33, 37 and 41, the claims are drawn to nucleic acid sequences of various sizes ranging from at least 8 bases up to about 235 kilobases. Said sequences do not specify any particular start or end points limited only by that they must comprise a sequence of consecutive bases of SEQ ID NO: 1 or 2 of at least 8 bases up to about 235 kilobases and that they must contain at least one of the polymorphic sites listed in Table number 1 of the instant specification. The written description in this case only sets forth the nucleic acid sequences of SEQ ID NO: 1 & 2 and the polymorphic sites of Table 1. Therefore the written description is not commensurate in scope with the claims drawn to the full genus of nucleic acid molecules encompassed by recitations of 'comprising at least 8 consecutive bases' and 'up to about 235 consecutive kilobases' of SEQ ID NO: 1 or 2.

Vas-Cath Inc. v. Mahurkar ((CAFC, 1991) 19 USPQ2d 1111), clearly states that 'Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*' (See *Vas-Cath* at page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.' (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see *Vas-Cath* at page 1115).

With the exception of the sequences defined by SEQ ID NO: 1 and 2, the skilled artisan cannot envision the detailed structure of the encompassed nucleic acid sequences comprising fragments of SEQ ID NO: 1 and 2, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, ((CAFC, 1993) 25 USPQ 2d 1601) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*,((CAFC, 1991) 18 USPQ2d 1016).

Furthermore, In *The Reagents of the University of California v. Eli Lilly* ((CAFC, 1997) 43 USPQ2d 1398), the court held that a generic statement which defines a genus of nucleic acids without distinguishing that genus from others, except by their function, does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that 'An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention.'

Therefore, nucleic acid molecules consisting of fragments of SEQ ID NO:1 or SEQ ID NO:2 comprising at least one of the polymorphic sites of Table 1, but not the full breadth of the claims generically drawn to comprising said fragments, meet the written description provision of 35 USC 112, first paragraph as provided by" the now finalized Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant's arguments filed February 1, 2001 have been fully considered but they are not persuasive.

Applicant has attempted to differentiate the facts in the instant case from those of the Court decisions. Applicant asserts that the instant case is differentiated from *Fiers* by the fact that *Fiers* is drawn to a method of identifying a gene while the instant case provides about 470 kilobases of sequence information. The instant case is not as well differentiated from *Fiers* as

Applicant appears to believe. Applicant's disclosure is concerned with the diagnosis of hereditary hemochromatosis (HH) by detecting a polymorphism located within said 470 kilobases of sequence information. The disclosure does not, however, teach which of the polymorphic site(s) is/are associated with the condition nor does it teach which form(s) of the polymorphism is/are associated with the pathology. It is readily apparent to anyone of ordinary skill in the art the gene of interest is not large enough to occupy the entire disclosed sequence, therefore the instant specification comes no closer to identifying a given gene. Applicant asserts that instant case overcomes the shortcomings found by the Court in *U.Cal.v.Lilly* because, unlike the case law, Applicant's claimed genera are identified by function and Applicant discloses specifically defined structural features by the disclosure of the 470 kilobases of sequence information and the disclosure of numerous polymorphic sites. Applicant fails to differentiate on both fronts. First of all the Court noted, as noted in Applicant's passage lifted from the case law, *Lilly* did distinguish the genus from others by function ("except by function"). Second, unless the HH-associated gene occupies the entire sequence and all the polymorphic sites are involved in the pathology, the structure of the gene Applicant intends to identify is no better defined because the instant specification does not disclose where in the 470 kilobases of disclosed sequence information the gene of interest is located, nor does it disclose which polymorphic sites are of predictive value.

4. Applicant is advised that the Utility Examination Guidelines (Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001) were published subsequent to the prior Office Action and the claims have been examined in view of these guidelines. New grounds of rejection under these guidelines which appear in this Office Action have necessitated that this action be made **NON-FINAL**.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 29-79 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible asserted utility or a well-established utility.

Claims 29-79 are drawn to polynucleotides comprising or consisting of 8-100 [claims 29-32, 45, 47, 49-54, 69-74], 18-100 [33-36, 46, 48, 55-60, 75-79], 100-235K [37-40, 61-64] or 300-235K [41-44, 65-68] nucleotides wherein the polynucleotide comprises at least one polymorphic site listed within a table. The claimed polynucleotides are not supported by either a specific and substantial asserted utility or a well-established utility. While the specification asserts that the utility of the claimed polymorphism-containing polynucleotides is for the diagnosis of hereditary hemochromatosis, the specification fails to provide objective evidence that all the genes which lie within the disclosed 235 kD nucleic acid sequences or all of the encompassed polymorphisms reasonably possess predictive value for hereditary hemochromatosis. A well-established utility is a specific, substantial, and credible utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. Identifying a 235 kD chromosomal DNA segment and all the polymorphisms therein which comprises a gene of interest does not endow the unidentified polynucleotide fragments with such a utility. The instant specification discloses several chromosomal polymorphic sites identified in the prior art as being associated with the condition (page 2, line 13 to page 3, line 6 for example, but the location of the HH gene is not identified within the 235 kD region, nor are the polymorphic sites within the 235 kD segment which are relevant to hereditary hemochromatosis identified. There is therefore no specific, substantial, or credible utility that is well-known, apparent, or implied by the relationship of the instant polynucleotide fragments to polynucleotides relevant to hereditary hemochromatosis.

The claimed polynucleotides also lack a specific or substantial utility. DNA fragments have no specific or substantial utility; their use to identify full-length sequences is a research use only. The utilities identified by the Applicant beginning on page 3 are also not specific or

substantial. While the association of a particular polymorphism with a pathology would be both specific and substantial, the specification does not identify the location of the HH gene within the large disclosed chromosomal fragments identified as SEQ ID NO:1 & 2, nor does the specification disclose which of the polymorphisms within the disclosed sequences are within or close enough to the HH gene in order to serve as relevant markers for a polymorphism useful for diagnostic purposes. The claimed polynucleotides therefore appear to be merely an attempt to narrow down the search area to find the HH gene and then identify the polymorphisms which are of diagnostic value. It is apparent that further research would be required to identify the gene associated with the hereditary hemochromatosis disease and for which any mutations would be of significance; the polynucleotides therefore lack a substantial utility. See Brenner v. Manson, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." A patent is therefore not a license to experiment. Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

7. Claims 29-79 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

8. No claim is allowed.

9. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The

Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2001 365-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
April 23, 2001

F. PIERRE VANDERVEGT
PATENT EXAMINER